UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044,405	01/11/2002	Paul H. Stypulkowski	11738.00026	8922

27581 7590 09/09/2005

MEDTRONIC, INC.
710 MEDTRONIC PARKWAY NE
MS-LC340
MINNEAPOLIS, MN 55432-5604

EXAMINER	
EVANISKO, GEORGE ROBERT	
ART UNIT	**PAPER NUMBER**
3762	

DATE MAILED: 09/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/044,405	STYPULKOWSKI, PAUL H.	
	Examiner	Art Unit	
	George R. Evanisko	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 May 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 5-9, and 18-23 are rejected under 35 U.S.C. 102(e) as being anticipated by Gliner (US 2002/0055762). Gliner shows in figures 6 and 8-10 the random variation of the frequency and changing of the amplitude based on the frequency within predetermined limits (pseudo-randomly varying) and strength-duration curves for the varying stimulation parameters to follow. For claims 6 and 7, since Gliner randomly changes the frequency and amplitude and does it over a wide range (as seen in figures 8 and 9), he inherently will produce a neuron-firing pattern having a plurality of different interspike intervals and selected from the group of normal, skew-right, skew-left, or bimodal. In addition, a varying of electrode polarity firing conditions would inherently change a spatial pattern of neurons affected since the electrodes are positioned in different locations. Also, the varying inherently avoids development of physiological tolerance due to the changing stimulation parameters over the large predetermined range.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gliner.

Gliner discloses the claimed invention except for measuring of the patients neuron strength-duration curve for a plurality of amplitudes at corresponding pulse durations and observing whether a desired outcome is achieved. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the neural stimulation system/method as taught by Gliner, with a measuring of the patients neuron strength-duration curve for a plurality of amplitudes at corresponding pulse durations and observing whether a desired outcome is achieved since it was known in the art that neural stimulation systems/methods have steps for measuring of the patients neuron strength-duration curve for a plurality of amplitudes at corresponding pulse durations and observing whether a desired outcome is achieved in order to maintain the stimulation capability of the electrical stimulation pulses substantially constant to provide a desired outcome.

Claims 1 8, 9, and 13-23 rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Mouine et al (2004/102820). Mouine states in paragraph 49 that the amplitude, frequency, and pulse duration are randomly varied to maintain a predetermined average and that these parameters define the amount of charge delivered to the nerve and therefore will inherently change a second stimulation parameter when the first stimulation parameter is changed in order to maintain the predetermined average. In addition, Mouine uses a disconnect module to attach the electrodes and to leave the electrodes in the body and therefore must inherently have some sort of lead to attach to the module.

In the alternative, Mouine discloses the claimed invention except for the changing of a second stimulation parameter based upon the first parameter being pseudo-randomly varied and upon a predetermined relationship between how the first parameter affects desirable values for the second parameter. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the neurostimulation system/method as taught by Mouine, with a changing of a second stimulation parameter based upon the first parameter being pseudo-randomly varied and upon a predetermined relationship between how the first parameter affects desirable values for the second parameter since it was known in the art that neurostimulation systems use a changing of a second stimulation parameter based upon the first parameter being pseudo-randomly varied and upon a predetermined relationship between how the first parameter affects desirable values for the second parameter to maintain the stimulation capability of the stimulation pulses substantially constant to provide therapy to the patient.

Claims 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Archer et al (6690974) or Pless (6466822).

Archer or Pless discloses the claimed invention and randomly or pseudo-randomly varying a combination of or multiple pulse parameters (columns 10 and 11 and columns 8 and 9, respectively) in a deep brain neural stimulation system (columns 18 and 19 and columns 6 and 11) except for the second stimulus parameter varied over a range based upon a predetermined relationship that specifies how changes in the first parameter affect the second parameter to avoid physiological tolerance. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the neural stimulation method and system as taught by Archer or Pless, with the second stimulus parameter varied over a range based upon a

predetermined relationship that specifies how changes in the first parameter affect the second parameter to avoid physiological tolerance since it was known in the art that neural stimulation methods and systems vary the second stimulus parameter over a range based upon a predetermined relationship that specifies how changes in the first parameter affect the second parameter to avoid physiological tolerance to provide pulse parameters that the tissue/nerve does not get accustomed to the specific electrical stimulation and provides the stimulation over a safe range of values, to overcome the problem of patients becoming physiologically adapted to a single or limited number of frequencies, and provide effective therapy for a large patient population.

Allowable Subject Matter

Claim 5 is allowed.

Response to Arguments

Applicant's arguments filed 5/2/05 have been fully considered but they are not persuasive. The arguments that Gliner does not teach changing a value of a second of the stimulation parameters based upon having pseudo-randomly varied the first stimulation parameter and much less doing so based upon a predetermined relationship that specifies how changes in the first parameter affect desirable values for the second parameter are not persuasive since Gliner teaches these claim limitations. Gliner specifically teaches "randomly" varying the frequency over a range (the claimed "pseudo-randomly varying") in paragraphs 46-57 and 41 (specifically 41 and 51). In addition, Gliner states in paragraphs 46-57, and shows in figures 6 and 8-10, that amplitude or duration are changed based on the frequency according to particular formulas (the examiner specifically pointed this out in the previous detailed action). Finally, it

does not matter if Gliner says the process "can" include a schedule, since this is just one/alternate embodiment of many that Gliner teaches and/or is what makes it a "pseudo" random variation.

The argument that Gliner and the 103 rejection of claims 3 and 4 does not provide any support showing that it was known in the art to measure the strength-duration curve for neural excitation..."for the use as a predetermined relationship to change a value of a second of the stimulation parameters based upon having pseudo-randomly varied a first stimulation parameter" is not persuasive since the claims do not state that the measured curve is "for the use as a predetermined relationship to change...parameter". The claims only state that the curve is measured (claim 3) and that a plurality of amplitudes are used to obtain a clinical outcome. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

The argument that Mouine does not disclose, teach, or suggest "changing a value of a second of the stimulation parameters...based upon a predetermined relationship that specifies how changes in the first parameter affect desirable values for the second parameter" is not persuasive since Mouine does disclose that claim limitation. Mouine states that both frequency AND ("and/or" in paragraph 49) amplitude are randomly varied and that the device keeps a predetermined average/charge. Therefore, any change in frequency or amplitude would inherently require a change in amplitude or frequency, respectively, since the predetermined average/charge must be maintained. In the alternative, the examiner provided a 103 rejection for that claim limitation. The prior art of Gliner is one example showing that it is well known.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Archer is another example of an implantable device that randomly varies stimulation parameters.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R. Evanisko whose telephone number is 571 272 4945. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571 272 4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

George R Evanisko
Primary Examiner
Art Unit 3762
9/6/5

GRE
September 6, 2005